K011617

JUN - 8 2001

Section 10 - 510(k) Summary of Safey and Effectiveness as required by 21 CFR 807.92(c)

10.1	**Submitted by**	Ferrania S.p.A. Viale della Libertà 57 17014 Ferrania Savona (Italy)
10.2	**Contact person**	Ing. Mannella Paolo Regulatory Manager +39 0195224055 (phone) +39 0195224546 (fax). E-mail: pmannella@ferraniait.com
10.3	**Date Summary Prepared:**	March 30, 2001
10.4	**Device name:**	**Common Name:** Medical Ink-jet printer **Trade name:** LifeJet™ Printer 400 **Classification Name:** Medical image hardcopy device (per 21 CFR 892.2040)
10.5	**Predicate device:**	KODAK DIGITAL SCIENCE 1200 Distributed Medical Imager (510(k) number: K983905) Eastman Kodak Company Health Imaging Division 343 State Street Rochester, NY 14650

10.6 Description of device

The LifeJet™ Printer 400 is an inkjet printer designed to produce high quality color and gray-scale referral medical images. Together with specifically designed medical paper and inks (LifeJet™ Medical Paper and LifeJet™ Medical Ink Jet Cartridges) the LifeJet™ Printer 400 forms the LifeJet™ 400 System, which is an innovative, convenient and work-flow improving medical printing platform, based on the state of the art inkjet technology, capable of delivering superior and reliable printed images for any medical documentation requirement.

10.7 Statement of intended use

The LifeJet™ Printer 400 is an ink jet printer designed to provide referral high quality color and/or gray scale hard copies of medical images generated by medical equipment.

10.8 Comparison with predicate device

The purpose and functionality of the Ferrania LifeJet™ 400 Printer are substantiallly equivalent to the KODAK DIGITAL SCIENCE 1200 Distributed

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The basis for the equivalence is that both of them are computer peripheral printing devices which print monochrome or color images on paper, using inkjet technology.

The only difference is that the LifeJet™ Printer 400 driver allows the user to format the print layout by printing one to eight images per page, in strips of two, either in portrait or landscape mode, as soon as they are available and while the diagnostic examination goes on.

The technological equivalence of the two printers and the equivalence in terms of their features is summarized in the table below.

Table of comparison of features of Predicate Device

Feature/ Specification	LifeJet™ Printer 400	Kodak Digital Science 1200 Distributed Medical Imager
Printing Technology	Ink-jet	Ink-jet
Operating System	Windows NT 4.0	Windows 95/98, NT 4.0
Printing Resolution	1200x1200 dpi	1200x1200 dpi
Tones	Color and gray scale	Color and gray scale
Number of Colors	256 x CMYK	256 x CMYK
Standards	UL, CSA, FCC, CE Mark, IEC 60601-1, Energy Star	UL, CSA, FCC, EN50082, CISPR 22, VCCI, CE Mark, C-Tick, Energy Star
Interfaces	Parallel: IEEE 1284	Parallel: IEEE 1284
Cartridges	Black LifeJet™ Medical Ink Jet Cartridge, Color LifeJet™ Medical Ink Jet Cartridges	DMI Ink cartridge 1 DMI Ink Cartridge 2, or DMI Black Cartridge
Printing Media	Coated paper	Coated paper Coated film (blue)
Sheet sizes	A4, A5, A6, US letter, 4"x6", personalized	A4, A5, A6, B5, Executive, Legal, US letter, 4"x6", 8"x10"
Supply Tray Capacity	50 sheets	45 sheets
RAM	2 MB	Not available

10.9 Performance testing

The tests carried out to measure the printing time and image quality for the LifeJet™ Printer 400 in comparison with the predicate device confirmed their substantial equivalence also in terms of performances.

Objective test procedures were established to measure:

- the time to print one 203x203 mm image of a SMPTE pattern (512x512 pixel),
- the printed maximum optical density,

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- the image mottling and bleeding @ 100% density.

10.6 Conclusion

Based on the analysis of the comparisons made between the LifeJet™ Printer 400 and the predicate device and on the results of performance test results, Ferrania S.p.A. concluded that the LifeJet™ Printer 400 is safe, effective and performs as well as or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ferrania S.P.A.
% Ms. Chantel Carson
Underwriters Laboratories Inc.
333 Pfingsten Road
NORTHBROOK IL 60062

Re: K011617
LifeJet™ Printer 400
Dated: May 15, 2001
Received: May 25, 2001
Regulatory Class: II
21 CFR 892.2040/Procode: 90 LMC

Dear Ms. Carson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Statement of Indications for Use

510(k) Number (if known) _____

Device Name: **LifeJet™ Printer 400**

Indications for Use:

The LifeJet™ Printer 400 is an ink jet printer designed to provide referral high quality color and/or gray scale hard copies of medical images generated by medical equipment.

The LifeJet™ Printer 400 has been developed to be used together with LifeJet™ Medical Paper and LifeJet™ Medical Ink Jet Cartridges to achieve the best quality medical images.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K011617